NRC OBSERVATION AUDIT REPORT NO. OAR-04-02, OBSERVATION AUDIT OF OFFICE OF QUALITY ASSURANCE AUDIT 04-DOE-AU-001 OF THE NATIONAL SPENT NUCLEAR FUEL PROGRAM

4/16/04

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Enclosure

1.0 INTRODUCTION

Staff from the U.S. Nuclear Regulatory Commission (NRC), Division of High-Level Waste Repository Safety, and the Center for Nuclear Waste Regulatory Analyses (CNWRA) observed the U.S. Department of Energy (DOE), Office of Environmental Management (EM) and Office of Civilian Radioactive Waste Management (RW) Audit 04–DOE–AU–001 on March 29–April 1, 2004, of the National Spent Nuclear Fuel Program (NSNFP) at the Idaho National Engineering and Environmental Laboratory (INEEL), Idaho Falls, Idaho. The objective of this audit was to evaluate NSNFP activities that impact safety or waste isolation with particular attention on activities that provide input for the Repository License Application (LA). The audit also evaluated the adequacy and effectiveness of the NSNFP Quality Assurance (QA) Program implementation for compliance to the requirements of the Office of Civilian Radioactive Waste Management's Quality Assurance Requirements and Description (QARD), DOE/RW–0333P, Revision 13. The NRC Observers (observers) assessed the effectiveness of the audit team and the audit process in achieving the DOE audit objectives.

2.0 MANAGEMENT SUMMARY

The audit team's goal was to assess the effectiveness of the following NSNFP activities:

- NSNFP Organization and Interfaces, Procedure Implementation, and QA Oversight
- Procurement of services from Government Sector Suppliers
- Standard Canister Qualification
- Spent Nuclear Fuel (SNF) Grouping and Radionuclide Inventory/Source Term Estimates
- Software Management
- Material Control Accountability
- Follow-up of Office of Quality Assurance (OQA) Audits, EM–ARC–01–13 and EM–ARC–02–10 Findings
- Other activities/data information generated and used to support the LA

The audit team identified two potential conditions adverse to quality (CAQ) with the implementation of the NSNFP quality program: the audit team also cited two recommendations for improvement in document control, and two noteworthy practices. Overall, the audit team determined the NSNFP quality program was satisfactorily implemented and effective.

The observers determined the audit team was effective in evaluating the adequacy and effectiveness of the NSNFP quality program. The observers agreed with the audit team's conclusions, findings, and process improvement recommendations.

3.0 AUDIT PARTICIPANTS

DOE Audit Team Members

Larry D. Vaughan, DOE/EM–3.2, Audit Team Leader
Carl E. Weber, RW OQA, Auditor
Robert A. Toro, Navarro Quality Services (NQS)/OQA, Auditor

James E. Flaherty, NQS/OQA, Auditor
John E. Scorah, DOE/EM–13, Auditor
Jefferson McLeary, Bechtel/SAIC/Integrated Science Solutions, Inc., Subject Matter Expert (SME)

Observers

Ted Carter, NRC, Team Leader
Joseph Petrosino, NRC, Senior QA Specialist
Randy Fedors, CNWRA, Technical Specialist
Tom Trbovich, CNWRA, QA Specialist

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The audit team conducted this audit in accordance with DOE procedures AP–18.4Q, DOE EM/RW Oversight Process, and LP–16.2Q, Management of Conditions Adverse to Quality for External Organizations. The audit team used the QARD and NSNFP procedures to generate the audit checklist. The observers followed NRC Manual Chapter 2410, Conduct of Observation Audits, July 12, 2000, while observing the audit.

4.1 Scope of the Audit

The scope of the audit included the following QARD elements:

Section 1.0	Organization
Section 2.0	QA Program
Section 3.0	Design Control
Section 4.0	Procurement Document Control
Section 5.0	Implementing Documents
Section 6.0	Document Control
Section 7.0	Control of Purchased Items and Services
Section 11.0	Test Control
Section 16.0	Corrective Action
Section 17.0	QA Records
Section 18.0	Audits
Supplement I	Software
Supplement III	Scientific Investigation
Supplement V	Control of Electronic Management of Data

The audit team considered other elements for the audit but determined that they were not applicable to the work performed by NSNFP.

The audit team also verified completion and effective implementation of corrective actions for conditions identified in previous RW audits, EM–ARC–01–13 and EM–ARC–02–10.

4.2 Conduct and Timing of the Audit

The observers determined that the audit was performed effectively and the audit team demonstrated sound knowledge of the applicable NSNFP procedures and QARD requirements. The audit team members conducted thorough interviews, challenged and questioned responses when appropriate, and effectively employed their checklists. The timing of the audit was not appropriate because the last evaluation of NSNFP had been conducted in September 2002, approximately 18 months earlier. The QARD required an audit be performed within 12 months of the last audit.

The audit team and observers held a caucus at the end of each day to discuss the audit status and any new and developing issues. The audit team met with NSNFP management each morning with observers present to discuss the current audit status and potential issues. The audit team issued an EM/RW Audit Issues form to document concerns each day that it presented to NSNFP management. This procedure allowed for good tracking, clarification, and resolution of issues.

4.3 Audit Team Qualification and Independence

The observers reviewed the qualifications for the Audit Team Leader and the auditors and determined that they were qualified and independent of the areas reviewed.

4.4 Examination of QA Elements

4.4.1 Organization

The NSNFP is composed of three interfacing organizations. The organizations are DOE NSNFP Program Management (PM), providing the project management and QA program direction; the NSNFP Project Support Organization operated by the INEEL Management and Operating (M&O) contractor, which performs technical work and administrative tasks in support of PM; and the NSNFP Quality Assurance Support organization, also operated by the INEEL M&O contractor, which provides QA program oversight and coordination with external interfaces for QA program related matters. These organizations perform activities in accordance with the NSNFP Quality Assurance Program Plan and the implementing procedures represented by the NSNFP QARD Requirements Matrix (DOE/SNF/MTX–001). Each organization has developed procedures to conduct their activities and implement the requirements of the QARD as applicable.

The NSNFP roles and responsibilities include: (1) primary interface between EM–SNF and RW; (2) advocate for SNF in the DOE complex; (3) management of DOE SNF repository related activities; (4) qualification of EM SNF site QA programs; (5) integration of technology development needs; and (6) augmented staff for repository analyses.

The audit team determined that the NSNFP organization is adequately described in the various procedures and that the QA organization has independent oversight of the NSNFP activities.

4.4.2 Quality Assurance Program

The audit team reviewed the QARD Requirements Matrix, several procedures from each NSNFP organization, and NSNFP Planning/QA Program Applicability Evaluations (PAE) to determine if proper reviews and approvals had been performed and QARD requirements had been incorporated.

The audit team noted two potential CAQs:

(i) The PAE did not provide adequate justification or rationale for activities determined to be nonquality-affecting work. Examples cited included PAE–007, Materials Analysis, and PAE–009, Technical Planning and Program Support.

(ii) The current QARD Matrix did not identify all applicable NSNFP implementing procedures for each QARD requirement.

The observers agreed with the audit team findings in this area.

4.4.3 Design Control

The audit team reviewed ten NSNFP documents to assess compliance with procedures PSO 3.03, Engineering Analysis, and 3.04, Engineering Documentation, including planning documents, program applicability evaluations, engineering design files, and NSNFP reports. NSNFP staff maintained that no design tasks were done as part of the NSNFP program. Rather, NSNFP staff provided input to Yucca Mountain Project design tasks through the documents produced by the NSNFP.

NSNFP procedure PSO 3.04 allows two methods of establishing traceability and transparency: engineering design analyses reports or scientific notebooks. Over the past 2 years, the NSNFP has relied mostly on the use of engineering documentation files and reports instead of scientific notebooks. The audit team found the NSNFP documents to be clearly and comprehensively written, which resulted in document transparency being identified as a noteworthy practice.

The SME audit team member assessed the integration of NSNFP activities with Yucca Mountain Project activities. Specifically, prior to the audit, a search of the Yucca Mountain database identified NSNFP documents cited in Yucca Mountain calculation reports, design documents, and analysis and model reports marked for inclusion in the LA. Only NSNFP reports cited as direct input (technical information or product output categories) were selected for further review by the audit team. NSNFP documents marked as privileged (e.g., classified Naval nuclear waste analyses) or providing support for reference-only information were excluded from further review.

The SME verified the traceability of information between NSNFP documents and direct input used in LA documents of the Yucca Mountain Project. Generally, translation of information was accurate, although one instance of an error in the NSNFP document being carried over to the Yucca Mountain Project document was found. A revision of the NSNFP report eliminated the

error, but the Yucca Mountain Project document will retain the error unless there is a revision prior to the LA submittal. The effect of the error is not considered by the audit team to be significant.

The observers agree with the audit team conclusion that transparency in NSNFP documents was noteworthy and that traceability to LA documents was accurate. The observers agree that the NSNFP documents were compliant with their procedures. Traceability of inputs to NSNFP documents, however, was not considered part of the audit team mission.

4.4.4 Procurement Document Control

NSNFP staff has not made any purchases from external organizations that required the initiation of an INEEL purchase order. Work was performed, however, by other internal DOE organizations through the use of a Task Management Agreement (TMA). The audit team reviewed TMA–05, Canister Basket Tasks, to be performed by the INEEL M&O contractor and TMA–09, Canister Weld/Repair System. The audit team noted that each of the TMA documents specified the QARD applicability and other specific contractual quality requirements. In addition, the audit team reviewed two PAE documents that were part of the internal work specification process that were used to identify the depth and scope of work.

The audit team did note a concern with some of the work being identified as "nonquality" especially with a new alloy (gadolinium) testing being performed by other DOE labs as identified in PAE–007, Materials Analysis. The nonquality designation would eliminate the need for private and government sector supplier evaluations. This concern was resolved through clarifying discussions with NSNFP staff. The audit team concluded that the process was conducted in accordance with the NSNFP procedure requirements.

The observers agree with the audit team findings in this area.

4.4.5 Software

From the three software packages used, NSNFP–GOTH, ORIGEN, and ABAQUS, the audit team had prior knowledge of activities on GOTH, and thus, it was not selected for review. Controls on ORIGEN were not evaluated because INEEL, not the NSNFP, had software control responsibility and because ORIGEN was an established code created by DOE. The audit team selected the ABAQUS software package for the audit review.

The audit team focused on the software test plan, report, and task management agreement with INEEL for the ABAQUS/Explicit Version 6.3-3 code. The agreement was required because the software was installed on two INEEL computers. ABAQUS/Explicit Version 6.3-3 is a commercial package that cannot be modified by the NSNFP. The software was used to analyze the mechanical integrity of waste canisters for potential transportation and handling accidents.

Components in the software plan and test report for ABAQUS/Explicit Version 6.3-3 appeared to directly follow the requirements of the NSNFP procedures 19.01, Software Control, and 3.04,

Engineering Documentation. Ten validation tests covering appropriate components of the software were performed by qualified NSNFP staff; the first two tests were identified as installation tests. The validation tests are repeated for each change in computers or relevant operating system change, and a new revision of the software report is produced; the software report is now in Revision 3.

The audit team was concerned with the degree of independence of the technical reviewer from the document production. Confusion arose concerning the terminology used on the Documentation Action Request form and on the document itself. The Document Action Request form required an initiator and a listing of technical reviewers. The document itself listed a responsible person's signature, which could be interpreted to be the report author. One case was cited where the technical reviewer was also listed as responsible staff on the report. Additional paperwork was found by the NSNFP Quality Engineer that indicated the technical reviewer did not write the document.

The observers agree with the audit team finding that the documentation package for the ABAQUS/Explicit Version 6.3-3 software was compliant with the NSNFP procedures.

4.4.6 Scientific Investigation

NSNFP staff maintained that no scientific investigations were performed during the time period applicable for this audit.

The audit team questioned three areas of work considered nonqualified activities and, thus, were not under the purview of this quality element of scientific investigations, including: (1) analyses with ABAQUS/Explicit on the mechanical integrity of canisters; (2) development of an American Society for Testing and Materials (ASTM) standard for a gadolinium-bearing alloy that may be added to some waste to be stored at Yucca Mountain as a neutron absorber; and (3) analyses intended to support characterization of SNF for LA of Yucca Mountain. The audit team agreed with the rationale presented by the NSNFP for all three activities, which is discussed below.

The model using ABAQUS/Explicit used a different design of canister than may be used later in Yucca Mountain Project activities. The NSNFP maintained the model will be used only to demonstrate the validity of the approach.

The gadolinium activity entailed the development of an ASTM standard to be used for procurement by Yucca Mountain of a low-carbon nickel-chromium-molybdenum-gadolinium alloy, which included characterization of the properties and behavior of the alloy. The NSNFP maintained that the ASTM acceptance process (committee and peer review) leads to a high quality product. Once the standard is accepted by ASTM, the Yucca Mountain Project may use the standard in procurement comments without further qualification.

Source term estimates were developed using the NSNFP electronic database and templates based on ORIGEN simulation results. The NSNFP maintains the calculations were used to support Yucca Mountain Project estimates of the source term in Total System Performance Assessment and, thus, were only indirectly used to support the LA. The observers agree with

the audit team conclusion that the NSNFP activities are compliant with the program procedures. Although not in the purview of this DOE audit, the observers noted a lack of integration between the Yucca Mountain Project and NSNFP controls on inputs and documents.

4.4.7 Control of the Electronic Management of Data

The audit team assessed compliance with QARD Section 2.1 by verifying (1) process controls are established to protect data from damage and destruction and data retrievability; (2) process for data storage consider media, conditions, location, retention time, security, and access; (3) the completeness and accuracy of the data input and subsequent changes to the data are maintained; and (4) the security and integrity of the data are maintained. During the review, the audit team identified two issues.

The SNF database had been classified as nonquality affecting in accordance with NSNFP procedures. Yucca Mountain procedure AP3.15Q, Managing Technical Product Input, however, accepts "numerical data from nuclear and government facilities regarding spent fuel" as established fact, that is, as qualified data. Since the NSNFP output data were used in quality-affecting Yucca Mountain technical reports, the audit team was concerned that the blanket acceptance of NSNFP data (without regard to the controls or lack of controls applied to its development) afforded by AP3.15Q was inappropriate. An auditor commented that a document change request had been initiated for AP3.15Q to rectify this concern.

The audit team was also concerned that the NSNFP database was not controlled using a qualified process. Procedure PSO 19.02, Management of the Spent Fuel Database, was written by the NSNFP for controlling electronic databases. Evidence of version control, input controls, and database integrity were clearly shown to the audit team. PSO 19.02, however, had not been incorporated into the Requirements Traceability Matrix, which formalizes the linkage to the QARD within the QA program. The audit team determined that appropriate controls would be in place if PSO 19.02 was followed, but there was no formalized requirement that PSO 19.02 had to be followed.

The observers agree with the audit team conclusion and consider the designation of all data and reports from the NSNFP as qualified to be a Yucca Mountain Project issue, not a compliance issue for the NSNFP.

4.5 Potential Audit Findings

The audit team identified two potential CAQs with the NSNFP quality program implementation:

1. The PAE does not document adequate justification or rationale when determining activities to be nonquality affecting.

2. Discrepancies noted with the NSNFP QARD Matrix included two procedures that were not referenced and found to be used in implementing QARD requirements, and a Quality Assurance Management Assessment being performed in fiscal year 2003 though being identified as not applicable.

The audit team made two recommendations:

1. Clarifying personnel responsible for document approvals in NSNFP procedures

2. Improvement in timeliness of QA records submittals from NSNFP staff with additional records protection actions that should be implemented during QA records processing

Noteworthy practices identified including the use of the Document Action Request form as a document traveler and the transparency of NSNFP reports to the Yucca Mountain Project.

5.0 NRC STAFF FINDINGS

5.1 NRC OBSERVATION SUMMARY

The observers determined that the audit team was effective in evaluating the NSNFP QA Program adequacy and effectiveness. The observers agreed with the audit team's conclusions, findings, and process improvement recommendations. The observers determined that the audit team members were qualified, independent of the areas being audited and had good knowledge and understanding of requirements.

5.2 NRC AUDIT OBSERVER INQUIRY

5.2.1 New Audit Observer Inquiry

No Audit Observer Inquiries (AOIs) were initiated during this audit.

5.2.2 Open NRC Audit Observer Inquiries

Since the AOIs initiated for other RW audits are not relevant to the NSNFP, they are not listed in this report. Open AOIs are being handled through separate correspondence between NRC and RW.